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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q64360

Ryuichi MORISHITA , et al.

Appln. No.: 09/856,374

Group Art Unit: 1632

Confirmation No.: 8301

Examiner: Qian Janice LI

Filed: May 21, 2001

For: GENE THERAPY FOR CEREBROVASCULAR DISORDERS

**STATEMENT OF SUBSTANCE OF INTERVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the in-person interview conducted on October 13, 2004:

**REMARKS**

An Examiner's Interview Summary Record (PTO-413) was completed by the Examiner and a copy was given to Applicants' representative following the interview. A copy was also mailed October 28, 2004.

During the interview, the following was discussed:

**1. Brief description of exhibits or demonstration:**

None.

**2. Identification of claims discussed:**

Claims 13-17.

**3. Identification of art discussed:**

Isner et al. (US 6,121,246 or WO 97/14307), Morishita et al. (US 6,248,722), Ghodsi et al. (Hum Gene Ther 1998; 9:2331-40), Yonemitsu et al. (Gene Ther 1997;4:631-8), Wang et al. (Biochem Biophy Comm 1998;244:449-54), Rosengart et al. (Circulation 1999;100:468-74), and Furlan et al. (Hum Gene Ther 1998;9:2605-17).

**4. Identification of principal proposed amendments:**

Possible amendments to the claims in order to distinguish HVJ-liposomes from cationic HVJ-liposomes.

**5. Brief Identification of principal arguments:**

Applicants' representatives argued that the claimed invention was not obvious because neither the genes (VEGF and HGF) nor the vector system (HVJ-liposomes) had been used in brain for gene therapy prior to the present invention.

The Examiner contended that even though muscle and brain are different tissues, VEGF and HGF effect endothelial cells, which are the same in both types of tissue. Therefore the Examiner asserted that successful use of VEGF and HGF via HVJ-liposomes for gene therapy in vascular endothelial cells in muscle teaches or suggests successful use for gene therapy in vascular endothelial cells in brain.

Applicants' representatives also argued that Yonemitsu teaches away from the use of HVJ-liposomes for gene therapy in brain.

**6. Indication of other pertinent matters discussed:**

None.

**7. Results of Interview:**

The Examiner agreed that if Applicants could distinguish the HVJ-cationic liposomes used by Yonemitsu from the HVJ-liposomes of the present invention, this would provide persuasive evidence that a person of ordinary skill in the art would not have reasonably expected HVJ-liposomes to function in the brain.

The Examiner also suggested that Applicants may wish to file a Supplemental Amendment in light of the interview.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

**It is believed that no petition or fee is required.** However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

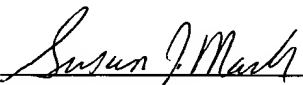
Respectfully submitted,

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WASHINGTON OFFICE

**23373**

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